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10/524,452

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Mitsuru Shiraishi

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

10/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/524,452 | Applicant(s) SHIRAISHI ET AL. | |
| | Examiner Celia Chang | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 15-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12-14 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 3, 9 and claims 1-2, 4-8, 10, 12-14 in the reply filed on Jun. 19, 2008 is acknowledged.

Claims 3, 9 and claims 1-2, 4-8, 12-14 reading on A is phenyl, thienyl or furanyl, B is piperidiny'/pyrrolidinyl is prosecuted. claims 11, 15-21 and the remaining subject matter of claims 1-2, 4-8, 12-14 are withdrawn from consideration per 37 CFR 1.142.

2. Claims 1-2, 4-6, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is very confusion what is the scope for R1 in claims 1-2, 4-6 with the convoluted proviso conditions. The R⁷ definition of claims 7-8 is not consistent with the proviso conditions when A is phenyl for R¹. Therefore the scope of the claims are confusing. Clarification is required based on explicit subgeneric description and antecedent basis from the specification.

Claims 12-14 are confusing. It is unclear what does the term "medicine" is referring to. Is it a therapeutic composition? Is it a method of using drug in treatment? The term medicine is a hybrid term. It is recommended that if the claims are drawn to pharmaceutical composition they be clearly delineated being containing an active ingredient selected from the claimed compounds in proper quantitative relationship i.e. therapeutically effective amount, together with at least one carrier to form the composition.

3. Claims 1-8, 10, 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making of compounds of claim 9, does not reasonably provide enablement for the broad scope of claims 1-8, 10, 12-14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As correlated to the above second paragraph rejection, it is unclear how the scope of the broad claims be ascertained since the convoluted substitution with enormous proviso condition

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makes it very difficult to know exactly what are the compounds being included in the claims and whether claim 10 process is operable for all the mix and matched compounds of the compound claims. To the extent of those compounds which are not exemplified, starting material, method of making and biological activity of such compounds are not found but required. Absent of starting material the public is offered mere language rather than enablement. In re Howarth 210 USPQ 689. Ex parte Moersch 104 USPQ 122. In addition, compounds having anti-cancer activity is highly unpredictable. The enormous compounds encompassed by the broad claims which are not exemplified lacks evidence that they all have the same activity as those exemplified and tested in the specification. Nexus is lacking but required.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Vicent CA 89:102701 or Salvati et al. CA 136:85823.

See RN 67533-15-7 or 385440-85-7 when Y11 and Y21 are acyl and ring A is phenyl compounds.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8, 10, 12-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Takaki et al. US 6,211,225.

See col. 25-28 table of examples wherein R1 is halo compounds and delineation of small genus with explicit exemplification of mono-halogen substitution. Therefore anticipation was found. Ex parte A 17 USPQ2d 1716.

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10, 12-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al. Org. Lett (recited on 1449), see compounds at p.899, #3-5.

Claims 1-6, 10, 12-14 rejected under 35 U.S.C. 102(e) as being anticipated by Schwink et al. US 7,223,788 or Labrie et al. US 2006/0287327.

It is noted that no certified translation of the priority document was provided in the record. The benefit of foreign priority is thus denied. The application date of the instant application is the PCT filing date Aug. 11, 2003. The Wang et al. reference is a 102(a) date reference and the two references Schwink or Labrie are therefore 102(e) date reference.

See anticipatory compound of Schwink et al. '788 col. 317-318 compound 634, R1 is an electron drawing group.

See anticipatory compound of Labrie et al. '327 at page 34 EM7676 ring B is optionally substituted piperidine.

7. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 1, 2008

/Celia Chang/
Primary Examiner
Art Unit 1625